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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,930	05/23/2006	Peter William Surman	D2026/20001	3207

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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	

NOTIFICATION DATE	DELIVERY MODE
03/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,930	SURMAN ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-45* is/are pending in the application.

4a) Of the above claim(s) *39-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 12/07/2009; and Information Disclosure Statement filed on 07/20/2009.

- Claims 27-45 are pending in the instant application.
- Claims 39-45 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 27-38) in the reply filed on 12/07/2009 is acknowledged. The traversal is on the ground(s) that stable aqueous composition of clozapine in not taught by the prior art. This is not found persuasive because EISHUN (JP 10-175865) teaches clozapine in 0.9% sodium chloride solution (see abstract), which reads on a stable aqueous composition of clozapine.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-33, 35, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by EISHUN (JP 10-175865).

Applicant's claims are directed to an aqueous composition comprising of: 0.1-10% of clozapine; buffers, such as sodium phosphate/sodium hydroxide, for a pH of 6-8; wetting agents, such as propylene glycol.

EISHUN teaches an aqueous composition comprising of: 0.5% clozapine (see abstract and [0014]); buffers, such as sodium phosphate, for a pH of 7.4 (see abstract); wetting agents, such as propylene glycol (see abstract). Additional disclosures include: 0.9% sodium chloride solution (see abstract), which reads on water; emulsified (see [0013]); suspending agents, such as carboxymethyl cellulose (see [0011]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over EISHUN (JP 10-175865) in view of HONMA et al (US 6,569,903), ALI et al (US 5,521,222) and HORLINGTON (US 4,425,346).

As discussed above, EISHUN teaches an aqueous composition comprising of: 0.5% clozapine (see abstract and [0014]); buffers, such as sodium phosphate, for a pH of 7.4 (see abstract); wetting agents, such as propylene glycol (see abstract). Additional disclosures include: 0.9% sodium chloride solution (see abstract), which reads on water; emulsified (see [0013]); suspending agents, such as carboxymethyl cellulose (see [0011]).

EISHUN does not teach using preservatives, such as methylparaben; glycerine, NaOH buffer, and xanthan gum.

HONMA teach ophthalmic compositions commonly use preservatives, such as methyl-hydroxybenzoate (see col. 7, line 62-65), which is methylparaben; isotonizing agents, such as glycerine and propylene glycol and polyethylene glycol (see col. 7, line 55-59); sodium hydroxide buffers for adjusting pH (see col. 8, line 40-42).

ALI teaches ophthalmic compositions commonly use preservatives, such as methylparaben (see col. 3, line 5-8); tonicity adjusting agent, which reads on isotonizing agents disclosed in HONMA, include glycerine and propylene glycol in the amount of 0.1-10% (see col. 3, line 13-16); NaOH buffering to a pH of 7.2 (see col. 3, line 35).

HORLINGTON teaches ophthalmic compositions commonly use suspending agents, such as carboxymethyl cellulose and xanthan gum (see col. 6, line 15-18).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate preservatives, such as methylparaben; glycerine, NaOH buffer, and xanthan gum into EISHUN's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because the

preservatives would extend the shelf-life of the composition; the glycerine and xanthan gum are functional equivalents of propylene glycol and carboxymethyl cellulose used in EISHUN; and adjusting pH using acid/base buffers, such as NaOH, are well-known. The person of ordinary skill in the art reasonably would have expected success because these are all commonly used ingredients in ophthalmic compositions.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618